5.0 510(k) Summary

I. SUBMITTER

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II. DEVICE

Name of Device: ENDORET® Kit
Common or Usual Name: Platelet and Plasma separator for bone graft handling
Classification Name: Automated blood cell separator (21 CFR 864.9245)
Regulatory Class: II
Product Code: ORG

III. PREDICATE DEVICE

ENDORET® Kit, BK130049

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ENDORET® Kit is composed of a set of components which permit the user to aseptically collect a small volume of peripheral whole blood from the patient into Collection tubes containing anticoagulant. Whole blood collected is later processed by centrifugation in order to separate into plasma fractions. The Platelet Rich Plasma (PRP) will be transferred by means of the Plasma Transfer Device to the Fractionation tube where it will be finally activated by the addition of the Activator prior to being mixed with autograft and/or allograft bone. The materials of the components consist of medical grade polymers, elastomers, rubbers and stainless

steel suitable for use in medical devices. The ENDORET® Kit components are sterilized either by radiation, ethylene oxide or autoclave. ENDORET® Kit Environment of Use is: Healthcare Facilities, Clinics and/or Hospitals. The ENDORET® Kit is a prescription use device.

V. INDICATIONS FOR USE

The ENDORET® KIT is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of peripheral blood at the patient´s point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the device features, intended use, laboratory data and other information demonstrate that the modified Biotechnology Institute ENDORET® Kit is substantially equivalent to the Biotechnology Institute ENDORET® Kit (BK130049). **Table 1** provides a comparison of the predicate and modified devices.

Although there have been some changes in the components contained for the ENDORET® Kit, kit presentation or solution supplier, there has been no change in general terms for the intended use or the indications for use of the ENDORET® Kit protocol optimized compared with the predicate ENDORET® Kit.

Table 1. Technological Characteristics Comparison:

Feature	Cleared ENDORET® Kit (BK130049)	Proposed Modified ENDORET® Kit (This submission)
Indications for Use	The system is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient´s point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The system is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of peripheral blood at the patient´s point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Product Classification	21 CFR 864.9245 (ORG)	21 CFR 864.9245 (ORG)

<table>
<tr><th>Feature</th><th colspan="2">Cleared ENDORET® Kit (BK130049)</th><th colspan="3">Proposed Modified ENDORET® Kit (This submission)</th></tr>
<tr><td>Procedure</td><td colspan="2">The patient’s blood is collected by venipuncture.

The whole blood is centrifuged and separated based on density.

Plasma fractions of interest are transferred to Fractionation Tubes. Activator is added to the platelet-rich plasma in the Fractionation Tubes.</td><td colspan="3">The patient’s blood is collected by venipuncture.

The whole blood is centrifuged and separated based on density.

Plasma fractions of interest are transferred to Fractionation Tubes. Activator is added to the platelet-rich plasma in the Fractionation Tubes.</td></tr>
<tr><td rowspan="6">Kit Components</td><td>PE</td><td>Blood Collection Set</td><td rowspan="2">Collection Tray (BBT)</td><td>PE</td><td>Blood Collection Set</td></tr>
<tr><td>TE9</td><td>BTI Collection Tube</td><td>TB9</td><td>BTI Collection Tube</td></tr>
<tr><td>TF9-EST</td><td>BTI Fractionation Tube</td><td rowspan="2">Fractionation Tray (OFT)</td><td>TP10</td><td>BTI Fractionation Tube 2</td></tr>
<tr><td>PTD2-EST</td><td>Plasma Transfer Device</td><td>PTD2</td><td>Plasma Transfer Device</td></tr>
<tr><td>GP31280SF</td><td>Syringe for activator</td><td colspan="2">GP31280SF</td><td>Syringe for activator</td></tr>
<tr><td>ENDORET-ACT</td><td>ENDORET® Activator</td><td colspan="2">ENDORET-ACT</td><td>ENDORET® Activator</td></tr>
<tr><td>System Design</td><td colspan="2">Open system.</td><td colspan="3">Open system.</td></tr>
<tr><td>Anticoagulant in Blood Collection Tube</td><td colspan="2">0.9 ml of Anticoagulant solution.</td><td colspan="3">0.4 ml of Anticoagulant solution.</td></tr>
<tr><td>Activator</td><td colspan="2">Required volume: 0.05 ml of Activator per ml of Plasma.</td><td colspan="3">Required volume: 0.02 ml of Activator per ml of Plasma.</td></tr>
<tr><td rowspan="2">Fractionation Tube Characteristics</td><td>Vacuum:</td><td>Pre-determined.</td><td>Vacuum:</td><td colspan="2">Manually generated.</td></tr>
<tr><td>Volume:</td><td>Approx. 9 ml.</td><td>Volume:</td><td colspan="2">Approx. 10 ml.</td></tr>
<tr><td>Centrifugation</td><td colspan="2">General purpose centrifuge.</td><td colspan="3">General purpose centrifuge.</td></tr>
<tr><td>Packaging Configuration</td><td colspan="2">Components included in non-sterile pouches and/or blisters plus individually packaged components.</td><td colspan="3">Components included in sterile and non-sterile trays plus individually packaged components.</td></tr>
</table>

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation of the modified ENDORET® Kit was conducted in accordance with FDA's Blue Book Guidance G95 "*Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*" and *ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*.

The principal modification of the proposed ENDORET® Kit in which new materials are introduced are limited to the new BTI Fractionation Tube. Taking into account product characteristics and by means of ISO 10993-1 which refers to the applicable biocompatibility tests for an external communicating device with blood path, indirect contact and with a limited duration of the contact (A; ≤ 24h) the biocompatibility tests described in **Table 2** were performed all with passing results:

Table 2. Biocompatibility Testing performed:

Biocompatibility Test	Standard
Acute Systemic Toxicity Test	ISO 10993-11
Cytotoxicity Test	ISO 10993-5
Delayed Hypersensitivity Test	ISO 10993-10
Haemocompatibility Test	ISO 10993-4
Intracutaneous Reactivity Test	ISO 10993-10
Pyrogen Testing	Ph. Eur. 8.2 <20614> USP: 37-NF32 <85> and 37-NF32<161> ANSI/AAMI ST72:2011

Bench Testing

A single center study was performed with blood collected from healthy human donors for processing into a platelet rich product. The following platelet concentrate quality tests were performed: Platelet concentration factor, Platelet yield and pH; In addition, platelet function assays conducted were: platelet aggregation, platelet activation and hypotonic stress. Furthermore, a clot integrity analysis to measure the retention of bone graft material after the composite clot is subjected to mechanical stress was also performed.

The results obtained in the study demonstrate substantial equivalence performance (non-inferiority) between the Test PRP and the Predicate PRP for all parameters evaluated.

Usability Testing

The study involved the application of the devices by a representative sample of volunteers. Volunteers were instructed to follow Endoret Kit instructions for use in order to generate the vacuum within TP10, the assembling of TP10 on PTD2 and the transfer of liquid contained within the Collection tube to the Fractionation tube using the PTD2. ENDORET Kit Usability was evaluated by a Questionnaire to be completed by the volunteers.

The device's usability was demonstrated based on the results obtained. The device is in compliance with the acceptance criteria established for all usability parameters evaluated.

VIII. CONCLUSIONS

The results of the Biocompatibility, Performance and Usability testing together with the comparison of similarities and differences between the modified ENDORET® Kit device and the predicate ENDORET® Kit demonstrate that the modified ENDORET® Kit device is substantially equivalent to the predicate device.